**TRANSMITTAL OF APPEAL BRIEF**Docket No.
OSTEONICS 3.0-322

In re Application of: Patrick Raugel

Application No.
10/007,130Filing Date
November 5, 2001Examiner
D. J. DavisGroup Art Unit
3731

Invention: HANDLING DEVICE FOR ACETABULAR BEARING LINER

TO THE COMMISSIONER FOR PATENTS:

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(908) 518-6318Dated: January 21, 2005

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Dated: January 21, 2005

Signature: 

(Raymond W. Augustin)

Docket No.: OSTEONICS 3.0-322
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Patrick Raugel

Application No.: 10/007,130

Group Art Unit: 3731

Filed: November 5, 2001

Examiner: D. J. Davis

For: HANDLING DEVICE FOR ACETABULAR
BEARING LINER

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal from the decision of the Examiner finally rejecting the claims which are the subject of this appeal. The Commissioner is hereby authorized to charge \$500.00 required by 37 C.F.R. 1.17(c) for filing the brief and any other fees that may be due and owing in connection with this response, to Deposit Account No. 12-1095.

I. REAL PARTY(IES) IN INTEREST

The real party in interest in this case is the assignee of record, Benoist Girard SAS, 203 boulevard de la Grande Delle B.P. 8, Herouville-saint clair, Cedex, France, as evidenced by the Assignment dated January 21, 2002 and recorded at reel 012639, frame 0496.

II. RELATED APPEALS AND INTERFERENCES

To the best of the current knowledge of Applicant, there are no related appeals or interferences pending before the United States Patent and Trademark Office regarding this United States Patent application.

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III. STATUS OF CLAIMS

Claims 1-13, and 18-27 are pending in the present application. A clean copy of the claims are attached hereto as Appendix I. The claims of Appendix I do not include any changes submitted in the Amendment After Final Rejection filed herewith.

IV. STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed on October 11, 2004, but was not entered. An Amendment After Final Rejection relating to the rejection of claims 9-13 under 35 U.S.C. § 112 second paragraph is included herewith.

V. SUMMARY OF CLAIMED SUBJECT MATTER

According to the present invention a handling device is provided to hold a bearing liner which is to be introduced into the socket of an acetabular cup. The handling device comprises a support provided with an alignment element on the acetabular cup and having an opening which has a deformable rim around the perimeter of the opening adapted to receive the outer circumference of the bearing liner to be inserted. The deformable rim may be in the form of a plurality of resiliently deformable elements which are deformed by and thereby hold the bearing liner in place.

Thus, a bearing liner, for example of the tapered type, is inserted into the opening in the support until the rim is engaged. The so held bearing liner can now be accurately located in the tapered socket utilizing the alignment element. Because the lower surface of the support rests against the upper rim of the acetabular cup, the bearing liner is not fully engaged. This is easily achieved by pushing the bearing liner downwards through the deformable rim of the opening in the support so that the liner is correctly inserted. The handling device is now free of the bearing liner and can be removed.

Preferably the alignment element on the acetabular cup is formed by a substantially flat lower surface surrounding the opening. The support can be in the form of a substantially flat plate and can be made from a sheet material, for example a synthetic plastics material. The perimeter of the opening in the support can have a castellated rim which thus assists the rim to deform when the bearing liner is pushed through it.

The device can also include an element for retaining the bearing liner in the opening in the support and this retainer can, for example, be provided by the deformable rim itself which is adapted to resiliently grip the bearing liner.

The retainer is formed by an extended portion of the support which is bent back across the upper rim of the bearing liner.

The retainer is provided with an opening of smaller dimensions than the upper outer rim of the bearing liner, the opening being aligned with the opening in the support when in use.

An operating handle is included which is adapted to manually deform the deformable portion to allow the handle to bear on the cup portion of the bearing liner to displace it from the support.

The invention also includes a handling device as set forth above which is located on a bearing liner and is incorporated in a sterile package. Thus, the bearing liner can be held sterile in the package, the bearing liner lifted out of the package by the handling device and used by the surgeon without further sterilization.

The invention is as shown in FIGS. 1 to 6 and includes a handling device according to present invention generally denoted as 1 for holding a bearing liner 2 which is to be introduced into a socket 3 of an acetabular cup 4 (FIG. 2) comprises a support in the form of a first portion 5 which is provided with an opening 6 which has a radially incised deformable rim 7. The bearing liner 2 may be made of ceramic and have a tapered outer surface designed to lockingly engage a complementary tapered inner surface in socket 3. Incisions or slits 9 extend around the circumference of rim 7 and extend radially outwardly to a diameter slightly larger than the largest outer diameter of bearing liner 2. The incisions 9 could be replaced by slots or castellations to provide the deformable rim. Opening 6 is adapted to receive the outer circumference 8 of bearing liner 2. This outer circumference 8 is tapered so that the bearing liner sits in opening 6 with its upper rim projecting in the manner shown in FIGS. 1 and 2. The relative diameters of liner 2 and rim 7 and choice of material of first portion 5 can be such that rim 7 is adapted to resiliently grip liner 2. The handling device also includes a retainer provided by a second portion 10 which has an opening 11 which is of smaller diameter than the upper outer circumference 12 of bearing liner 2.

In the preferred embodiment, second portion 10 forms an extension of first portion 5 and they are hinged together at 13 by any suitable hinge construction. In a preferred embodiment, as

shown in the drawings, the first and second portions are formed as a try hinged at its center. First portion 5 has a projecting handle 14 which is repeated in second portion 10 by a handle 15.

The first and second portions may conveniently be made from sheet material, for example a synthetic plastics material such as PETG copolyester film made by LUSTRO and about 0.7 mm thick. The thickness of the material required will depend upon the characteristics of the material used. The lower surface 16 of first portion 5 is substantially flat when it is in position, as shown in FIG. 1 to act as means for alignment on acetabular cup 4. Due to the resilience of the thin sheet material however second portion 10 can be bent over the upper rim of the bearing liner so that the handles 14 and 15 are closely adjacent, as shown in FIG. 6, and this assists in maneuvering the device when in use and retains the bearing liner in place.

In order to assist handling of the device bosses 17 are provided on the handles 14 and 15 as it is most clearly shown in FIG. 5.

FIG. 6 shows how the handle device can be located on a bearing liner which has been incorporated into and sealed within a sterile package. The same reference numerals are used to indicate similar parts to those used in FIGS. 1 to 5 and it will be seen that second portion 10 has been moved down so that it can now lie flat against the upper rim 12 of the bearing liner.

VI. ISSUES

1. Whether claims 1-2, 5-13, and 18-27 are patentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,302,286 to *Witherspoon*.

2. Whether claims 1-4, 7-13, 18, 20, 22 and 26 are patentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Design Patent 353,328 to *Nuffer*.

3. Whether claims 1-4, 7-13, 18, 20, 22 and 26 are patentable under 35 U.S.C. § 103(a) as being obvious over U.S. Design Patent 353,328 to *Nuffer*.

4. Whether claims 9-13 are patentable under 35 U.S.C. § 112, second paragraph.

VII. GROUPING OF CLAIMS

With regard to the rejection over *Witherspoon* and *Nuffer* the rejection of claims 1 and 18 do not stand together. Claim 1 distinguishes over *Witherspoon* and *Nuffer* by claiming a handling device having a deformable rim for receiving the outer circumference of the bearing liner. Claim 18 includes a handle portion plus a plurality of resiliently deformable elements for gripping the bearing liner which elements are not present in claim 1.

Claims dependent off of claim 1 stand or fall with claim 1. The rejection of claim 27 does not stand with claim 18, from which it depends because the prior art does not show a hinged joint which joint forms part of a handle. This element is not claimed in claim 1 thus claim 27 does not stand or fall with claim 1.

VIII. APPENDIX

A first appendix containing a clean copy of all of the claims involved in the appeal prior to entry of the response under 37 C.F.R. § 1.116 filed herewith is attached at the end of this brief.

IX. ARGUMENT

A. U.S. Patent 6,302,286

The Examiner rejected claims 1-2, 5-13, and 18-27 as being anticipated by U.S. Patent 6,302,286 to *Witherspoon*. *Witherspoon* shows a baby bottle nipple cover having a ring 2 connected to cap 3 by a tether 26. The Examiner considers this structure to be a "handling" device although nowhere in the specification of the '286 patent is this structure described as such. Furthermore, during normal use, a baby bottle is grasped by the barrel. As understood in the orthopaedic art, a handle is an instrument part designed to be gripped by the hand of a surgeon so that the surgeon may control the orientation of the instrument. No such handle is provided by element 2, 3 and 26 of *Witherspoon* U.S. Patent 6,302,286.

Furthermore, Applicant considers the preamble of claim 1 to be a limitation of claim 1 which distinguishes over *Witherspoon*. Clearly, various elements in the body of the claim would lack antecedent basis had it not been for the recitation of these elements in the preamble. For example, the terms "handling device", "acetabular cup" and "bearing liner" in the body of claim 1 all have their antecedent basis in the preamble. In addition, the preamble of claim 1 gives life and meaning to the claims and as such define limitations of the claim which are intended to be included as part of the invention. Furthermore, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation. See *Catalina Marketing International, Inc. v. Coolsavings.com Inc.* 289 Fed3d 801, 62 U.S.P.Q. 2d 1781 (Fed. Cir. 2002).

The body of claim 1 further includes the limitation that the handling device includes a support with means for aligning the handling device with the acetabular cup and an opening for receiving the bearing liner. The bearing liner is also referred to at various later points in the

body of the claim. These limitations would have no meaning without the preamble. Consequently, Appellant does not believe that the device of claim 1 is anticipated by the *Witherspoon* reference which has no structure which can function as a handling device for holding a bearing liner to be introduced into the socket of an acetabular cup since there is no teaching of a bearing liner and no structure which can hold such a bearing and obviously no acetabular cup.

Applicant indicated in his Response After Final Rejection filed on October 11, 2004 (not entered) that the preamble can act as a limitation to distinguish over the prior art if it gives life and meaning to the remainder of the claim which is the case in this situation. That the preamble can be a claim limitation is stated in *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, 327 F.3d 1364, 66 U.S.P.Q. 2d 1631 (Fed. Cir. 2003). Since the preamble of claim 1 provides antecedence for the ensuing claim language such as the "bearing liner" this has been held to limit the scope of the claims to include the limitations in the preamble *see* for example, *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 65 U.S.P.Q. 2d 1981 (Fed. Cir. 2003). A cover for a nipple on a baby bottle is not a handling device for an acetabular cup bearing and thus can not anticipate claim 1.

In addition, even if one assumes that the cover 1 of *Witherspoon* is, as considered by the Examiner, to be the claimed second portion, it does not appear to be planar as required by claim 1. Consequently, even if the preamble and claim limitations relating to the introduction of a bearing liner into an acetabular cup were ignored, the remainder of the claim is not anticipated by the '286 patent since there is no planar second portion pivotally coupled to the first portion as claimed. The Examiner's position that the ring 2 comprises a handling device is an unreasonable interpretation of the function of ring 2 and tether 26 which is merely to hold the cover on the bottle prior to placing it over the nipple.

Claim 18 includes the bearing liner and the shell in the body of the claim which elements find their antecedent basis in the preamble of the claim. The Appellant reiterates the above arguments with regard to claim 18

In addition, claim 18 requires that the perimeter of the support resiliently grip the liner adjacent the open end thereof which is not necessarily the case as the projecting fins 8 of the '286 patent which are taught to be flexibly rigid to adapt to the exterior surface of a variety of baby bottles (col. 6, lines 23-34) which, it is submitted, does not specifically teach resiliently gripping each of the bottles. There is no teaching that each of the different diameter bottles be

"resiliently gripped" as claimed by merely that the diameter may be "adapted" which can be accomplished by permanently bending the "flexibly rigid" fins 8.

With regard to claim 27 *Witherspoon* does not teach any structure which could be considered a hinged joint which forms part of a handle. The tether 26 nor the ring 2 can reasonably be considered a handle.

Thus the rejection of the claims as being anticipated by *Witherspoon* should be withdrawn.

B. U.S. Design Patent 353,328

The Examiner rejected claims 1-4, 7-13, 18, 20, 22 and 26 as being anticipated by U.S. Design Patent 353,328 to *Nuffer*. *Nuffer* shows a soda can cover. As discussed above with regard to *Witherspoon* it is Applicant's position that the limitations of the preamble are included in the claim and therefore the *Nuffer* reference does not disclose the claimed instrument for aligning a liner in an outer shell of an acetabular cup. Furthermore, *Nuffer* does not teach a ring with a deformable rim (claim 1) for gripping the soda can with the ring opening and certainly does not teach any of the resiliently deformable elements claimed in claim 18. *Nuffer* does not teach a liner for receiving a bearing element. Nor does the *Nuffer* patent show any structure which could reasonably be considered to be a handle portion as claimed in claim 18. Thus none of the claims are anticipated by *Nuffer* and the anticipation rejection should be withdrawn.

C. Obviousness over *Nuffer*

The Examiner rejected claims 1-4, 7-13, 18, 20, 22 and 26 as being obvious over *Nuffer*. Clearly, *Nuffer* is not analogous prior art for the purpose of analyzing the obviousness of the subject matter at issue. In order to rely on a reference as a basis for rejection of an Applicant's invention, the reference must either be in the field of the Applicants endeavor or be reasonably pertinent to the problem which the inventor was concerned *see in re Oetiker*, 997 Fed2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992). The problem to be solved in both *Witherspoon* and *Nuffer* is a way to hold a cap on a tubular barrel. The problem applicant intends to solve is aligning a liner in an implanted outer shell of an acetabular cup via a tapered male surface adjacent an open end of the liner for insertion into a complementary tapered female surface on the shell. This, of course, has nothing to do with covering an opening in a baby bottle or a soda can. Consequently, one of ordinary skill in the orthopaedic art would not look to the soda can cover art to solve the bearing shell alignment problem. Therefore, Applicant does not consider

his acetabular cup bearing liner obvious over *Nuffer* and the rejection of the claims should be withdrawn.

X. REJECTION OF CLAIMS 9-13 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

In the Final Office Action, the Examiner rejected claims 9-13 as being indefinite because claim 9 recited a retainer whereas claim 1 recited a "planar second portion". Applicant has included an Amendment After Final Rejection to overcome this rejection. The Examiner is requested to enter this amendment to remove this issue from the appeal since the amendments place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

XI. CONCLUSION

Appellant requests that the rejection of the claims over *Witherspoon* and *Nuffer* be withdrawn on the basis that the claims are directed towards a device for aligning a bearing liner in an acetabular cup shell which is neither anticipated nor obvious over the baby bottle nipple cover (*Witherspoon*) or soda can cover (*Nuffer*) relied upon by the Examiner.

Dated: January 21, 2005

Respectfully submitted,

By 

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APPENDIX I - CLAIMS

1. (previously presented) A handling device for holding a bearing liner which is to be introduced into the socket of an acetabular cup comprising a support provided with means for aligning said handling device with said acetabular cup and having an opening which has a deformable rim adapted to receive the outer circumference of the bearing liner to be inserted, said support having a planar first portion including said opening and a planar second portion pivotally coupled to said first portion, said planar second portion pivotal about a pivot point from a first position oriented at an angle to said plane of said first portion to a second position parallel to said plane of said first portion and overlying an upper outer rim of said bearing liner.
2. (previously presented) The handling device as claimed in claim 1 wherein the means for alignment with said acetabular cup are formed by a substantially flat lower surface surrounding said opening.
3. (original) The handling device as claimed in claim 1 wherein said support is in the form of a substantially flat plate.
4. (original) The handling device as claimed in claim 1 wherein said support is made from a sheet material.
5. (original) The handling device as claimed in claim 1 wherein said support is made from a synthetic plastics material.
6. (previously presented) The handling device as claimed in claim 1 wherein the support has a castellated rim surrounding said opening.
7. (original) The handling device as claimed in claim 1 further comprising means for retaining the bearing liner in the opening in the support.
8. (original) The handling device as claimed in claim 7 wherein said retaining means are provided by said deformable rim which is adapted to resiliently grip the bearing liner.
9. (original) The handling device as claimed in claim 7 wherein said retaining means are provided by a retainer adapted to extend across the upper rim of the bearing liner.
10. (original) The handling device as claimed in claim 9 wherein means are provided for securing the retainer to the support.

11. (original) The handling device as claimed in claim 9 wherein said retaining means are formed by an extended portion of the support which is bent back across the upper rim of the bearing liner.

12. (previously presented) The handling device as claimed in claim 9 wherein said opening of said retainer is of smaller dimensions than the upper outer rim of the bearing liner, said opening being aligned with the opening in the support when in use.

13. (original) The handling device as claimed in claim 9 wherein said retainer is formed with a manually deformable portion which is aligned with said opening in the support when in use.

14. (cancelled)

15. (cancelled)

16. (cancelled)

17. (cancelled)

18. (previously presented) An instrument for aligning a liner and an outer shell of a two-piece prosthetic acetabular cup, the liner having a tapered male surface and an open end for receiving a bearing element and a shell having a complimentary tapered female surface comprising:

a retainer having a first portion with an opening having a perimeter for resiliently gripping the liner adjacent the open end thereof, the perimeter being in the form of a plurality of resiliently deformable elements, said retainer first portion including a handle portion for allowing the alignment of the tapered male surface in the liner with the tapered female surface on the shell said retainer having a second portion pivotally coupled to said first portion and pivotal from a position parallel to said opening to a position angled with respect to said opening.

19. (original) The instrument as set forth in claim 18 wherein the retainer is made of plastic.

20. (original) The instrument of claim 19 wherein the perimeter of the retainer surrounds an inner opening sized to receive an outer perimeter of the liner.

21. (original) The instrument of claim 20 wherein the resiliently deformable elements are formed by slits in said plastic extending radially outwardly from said inner perimeter of said opening.

22. (previously presented) The instrument as set forth in claim 18 wherein said second portion contacts said liner at the open end thereof for preventing said liner from

moving out of engagement with said resilient elements upon insertion of said liner into said shell.

23. (original) The instrument as set forth in claim 22 wherein the retainer is made of plastic.

24. (original) The instrument of claim 23 wherein the perimeter of the retainer surrounds an inner opening sized to receive an outer perimeter of the liner.

25. (original) The instrument of claim 24 wherein the resiliently deformable elements are formed by slits in said plastic extending radially outwardly from said inner perimeter of said opening.

26. (original) The instrument as set forth in claim 22 wherein said first and second portions are connected by a hinged joint.

27. (original) The instrument as set forth in claim 26 wherein said hinged joint forms part of said handle.

28. (cancelled)

29. (cancelled)

30. (cancelled)

31. (cancelled)

32. (cancelled)

33. (cancelled)